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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,951

04/20/2006

Brian Anderton

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

01/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/562,951	<b>Applicant(s)</b> ANDERTON ET AL.	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1656	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 January 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 10 November 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 22,23,26,27,32,36,38,39,41,42 and 55.
- Claim(s) withdrawn from consideration: 31,33-35,40,43-46,53 and 54.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/David J. Steadman/  
Primary Examiner, Art Unit 1656

Continuation of 3. NOTE: Applicant's amendment after final rejection, filed on 1/12/10, is acknowledged. While the amendment would appear to obviate the outstanding objections to claim 22, the objection to claim 55 as not ending with a period, the rejections under 35 U.S.C. 112, first and second paragraphs, and the rejection of claims 23 and 27 under 35 U.S.C. 103(a), the amendment has not been entered for reasons that follow. The rejection of claim 27 under 35 U.S.C. 103(a) was based on the interpretation of the recited "derivative" of "full length tau protein" of SEQ ID NO:2 as encompassing a fusion of SEQ ID NO:2 with, e.g., a polyhistidine tag, as taught by the reference of Ford. However, by amendment to claim 27 to limit the tau protein to "a fragment of SEQ ID NO:2", this interpretation no longer applies, thus requiring the examiner to search for "a fragment of SEQ ID NO:2" with respect to the claimed method. In the interest of compact prosecution, it is noted that the examiner would likely enter the amendment if claim 27 were canceled.

Continuation of 11. does NOT place the application in condition for allowance because: The request for reconsideration in the reply filed on 1/12/10 has been fully considered, however, the amendment does not place the application in condition for allowance. The amendment to the claims filed on 1/12/10 has not been entered because the claims as amended necessitate a new search as noted above. See MPEP § 714.13. Applicant's arguments in the amendment filed on 1/12/10 have been fully considered. However, in view of the non-entry of the amendment, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Office action mailed on 5/12/09 for the reasons of record stated therein.

In the interest of compact prosecution, it is noted that the amendment would not appear to overcome the objection to claim 55 as not having an "and" prior to "S435" and the rejections of claims 22, 26, 32, 36, 38-39, 41-42, and 55 under 35 U.S.C. 103(a) as set forth in items [13], [17], and [19], at p. 5, p. 12, and p. 19, respectively, of the Office action mailed on 5/12/09. Beginning at p. 13 of the instant remarks, applicant traverses the rejections under 35 U.S.C. 103(a), arguing the combination of references fails to teach each and every element of the claims, specifically, the elected species of S289 of tau as a CK1 phosphorylation site. However, this is not found persuasive. It is noted that applicant appears to emphasize the citing of a combination of 13 references. However, it is noted that while the examiner has cited 13 references in the rejection, the teachings of several of the references are duplicative, but were cited to establish the relationship between CK1 and tau and exploiting this relationship for a therapeutic purpose were well known in the prior art at the time of the invention, and to further establish that phosphorylation detection methods using a full-length tau protein were well known in the prior art at the time of the invention. Although applicant asserts the prior art fails to disclose CK1 phosphorylation of tau at S289 (the elected species), the examiner maintains the position that by screening for inhibitors of tau phosphorylation by CK1, one would have necessarily practiced the claimed method, particularly by analyzing the phosphorylation state of full length tau according to detection methods as taught by, e.g., Hasegawa, Hanger, and Morishima. By doing this, one of ordinary skill in the art would be "determining whether...the candidate substance...inhibits phosphorylation of tau protein...at...S289". One of ordinary skill in the art would have been motivated to analyze the phosphorylation state of full-length tau by CK1 because the prior art recognizes that there are numerous tau phosphorylation sites and that "both direct and immunological evidence...indicates that there are other sites of phosphorylation in...tau that have not yet been identified" (Hanger, p. 2474, column 1). .